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PATENT

Customer No. 22,852

Attorney Docket No. 05394.0020

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	)	
Stewart et al.	)	Group Art Unit: Not assigned
Application No.: 10/505,405	)	Examiner: Not assigned
Filed: August 24, 2004	)	
For: DELETED SEQUENCE IN M. TUBERCULOSIS, METHOD FOR DETECTING MYCOBACTERIA USING THESE SEQUENCES AND VACCINES	)	Confirmation No.: Not assigned

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicants bring to the attention of the Examiner the documents on the attached listing. This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application.

Copies of the listed documents are attached. The attached documents were cited in the International Search Report in the corresponding PCT application No. PCT/IB03/009864 filed March 13, 2003, the European Search Report in the corresponding European application No. EP 02 290 458.5, filed February 24, 2002, as well as in this application.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: December 8, 2004

By: 

Kenneth J. Meyers  
Reg. No. 25,146  
Phone: 202-408-4033  
Fax: 202-408-4400

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	4	Application Number	10/505,405
				Filing Date	August 24, 2004
				First Named Inventor	Stewart Cole
				Art Unit	Not assigned
				Examiner Name	Not assigned
				Attorney Docket Number	05394.0020-00000

## U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

zExamine r Initials	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-6,291,190 B1	September 18, 2001	BEHR ET AL.	

**Note: Copies of the U.S. Patent Documents are not Required in IDS filed after October 21, 2004**

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation <sup>6</sup>
		PCT WO 00/55362	September 21, 2000	COLE ET AL.		

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation <sup>6</sup>
		International Search Report in the corresponding PCT application No. PCT/IB03/009864 filed March 13, 2003.	
		European Search Report in the corresponding European application No. EP 02 290 458.5, filed February 24, 2002	
		COLE ET AL., "Deciphering the biology of <i>Mycobacterium tuberculosis</i> from the complete genome sequence, <i>Nature</i> , Vol. 393, 11 June 1998.	
		COLE ET AL., "Deciphering the biology of <i>Mycobacterium tuberculosis</i> from the complete genome sequence", <i>DATABASE GENBANK, NCBI</i> , whole document (Nature 393, 537-544 (1998))	
		MAHAIRAS ET AL., "Molecular Analysis of Genetic Differences between <i>Mycobacterium bovis</i> BCG and Virulent <i>M. bovis</i> ", <i>Journal of Bacteriology</i> , Vol. 178, No. 5, March 1996, pp. 1274-1282, American Society for Microbiology.	
		GORDON ET AL., "Identification of variable regions in the genomes of tubercle bacilli using bacterial artificial chromosome arrays", <i>Molecular Microbiology</i> (1999) 32(3), pp. 643-655, 1999 Blackwell Science Ltd.	
		SREEVATSAN ET AL., "Restricted structural gene polymorphism in the <i>Mycobacterium tuberculosis</i> complex indicates evolutionarily recent global dissemination", <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 94, pp. 9869-9874, September 1997.	
		BROSCH, R. ET AL., "A new evolutionary scenario for the <i>Mycobacterium tuberculosis</i> complex", <i>PNAS</i> , Vol. 99, No. 6, March 19, 2002.	
		BROSCH ET AL., "A new evolutionary scenario for the <i>Mycobacterium tuberculosis</i> complex", <i>DATABASE GENBANK, NCBI</i> , whole document (PNAS 99(6) 3684-3689 (2002))	
		BODDINGHAUS ET AL., "Detection and Identification of <i>Mycobacteria</i> by Amplification of rRNA", <i>Journal of Clinical Microbiology</i> , Vol. 28, No. 8, August 1990, pp. 1751-1759, American Society for Microbiology.	
		SREEVATSAN ET AL., "Restricted structural gene polymorphism in the <i>Mycobacterium tuberculosis</i> complex indicates evolutionarily recent global dissemination", <i>Microbiology, Proc. Natl. Acad. Sci. USA</i> , Vol. 94, pp. 9869-9874, September 1997.	
		STEAD ET AL., "When Did <i>Mycobacterium tuberculosis</i> Infection First Occur in the New World?", <i>Am J Respir Crit Care Med</i> , Vol. 151, pp. 1267-1268, 1995.	
		BEHR ET AL., "Comparative Genomics of BCG Vaccines by Whole-Genome DNA Microarray", <i>Reports, Science</i> , Vol. 284, pp. 1520-1523, May 28, 1999.	
		BROSCH ET AL., "Genomic Analysis Reveals Variation between <i>Mycobacterium tuberculosis</i> H37Rv and the Attenuated <i>M. tuberculosis</i> H37Ra Strain", <i>Infection and Immunity</i> , Vol. 67, No. 11, Nov. 1999, pp. 5768-5774, American Society for Microbiology.	
		KREMER ET AL., "Comparison of Methods Based on Different Molecular Epidemiological Markers for Typing of <i>Mycobacterium tuberculosis</i> Complex Strains: Interlaboratory Study of Discriminatory Power and Reproducibility", <i>Journal of Clinical Microbiology</i> , Vol. 37, No. 8, August 1999, pp. 2607-2618.	
		SUPPLY ET AL., "Automated High-Throughput Genotyping for Study of Global Epidemiology of <i>Mycobacterium tuberculosis</i> Based on <i>Mycobacterial</i> Interspersed Repetitive Units". <i>Journal of Clinical</i>	

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 4

Application Number 10/505,405  
 Filing Date August 24, 2004  
 First Named Inventor Stewart Cole  
 Art Unit Not assigned  
 Examiner Name Not assigned  
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## NON PATENT LITERATURE DOCUMENTS

	Microbiology, Vol. 39, No. 10, , pp. 3563-3571, October 2001	
	VAN SOOLINGEN ET AL., "DNA Fingerprinting of <i>Mycobacterium tuberculosis</i> " <u>Methods in Enzymology</u> , Vol. 235, pp. 196-205, Academic Press, Inc. 1994.	
	HEYM ET AL., "Implications of multidrug resistance for the future of short-course chemotherapy of tuberculosis: a molecular study", <u>The Lancet</u> , Vol. 344, pp. 293-298, July 30, 1994.	
	SCORPIO ET AL., "Rapid Differentiation of Bovine and Human Tubercle Bacilli Based on a Characteristic Mutation in the Bovine Pyrazinamidase Gene", <u>Journal of Clinical Microbiology</u> , Vol. 35, No. 1, pp. 106-110, January 1997, American Society for Microbiology.	
	SREEVATSAN ET AL., "Identification of a Polymorphic Nucleotide in <i>oxyR</i> Specific for <i>Mycobacterium bovis</i> ", <u>Journal of Clinical Microbiology</u> , Vol. 34, No. 8, pp. 2007-2010, August 1996, American Society for Microbiology.	
	VAN EMBDEN ET AL., "Genetic Variation and Evolutionary Origin of the Direct Repeat Locus of <i>Mycobacterium tuberculosis</i> Complex Bacteria", <u>Journal of Bacteriology</u> , Vol. 182, No. 9, pp. 2393-2401, May 2000, American Society for Microbiology.	
	VAN SOOLINGEN ET AL., "A Novel Pathogenic Taxon of the <i>Mycobacterium tuberculosis</i> Complex, Canetti: Characterization of an Exceptional Isolate from Africa", <u>International Journal of Systematic Bacteriology</u> , Vol. 47, No. 4, pp. 1236-1245, October 1997, International Union of Microbiological Societies.	
	PAPA ET AL., "Serological Specificity of <i>Mycobacterium tuberculosis</i> Glycolipids", <u>Acta Leprologica</u> (1989), Vol. 7 (Suppl. 1), pp. 98-101.	
	WELLS, A.Q., "Tuberculosis in Wild Voles", <u>The Lancet</u> , p. 1221, May 22, 1937.	
	VAN SOOLINGEN ET AL., "Diagnosis of <i>Myobacterium microti</i> Infections among Humans by Using Novel Genetic Markers", <u>Journal of Clinical Microbiology</u> , Vol. 36, No. 7, pp. 1840-1845, July 1998, American Society for Microbiology, 1998.	
	BRODIN ET AL., "Bacterial Artificial Chromosome-Based Comparative Genomic Analysis Identifies <i>Mycobacterium microti</i> as a Natural ESAT-6 Deletion Mutant", <u>Infection and Immunity</u> , Vol. 70, No. 10, pp. 5568-5578, October 2002, American Society for Microbiology.	
	ARANAZ ET AL., " <i>Mycobacterium tuberculosis</i> subsp. <i>Caprae</i> subsp. Nov.: a taxonomic study of a new member of the <i>Mycobacterium tuberculosis</i> complex isolated from goats in Spain", <u>International Journal of Systematic Bacteriology</u> (1999), Vol. 49, pp. 1263-1273, IUMS.	
	VAN SOOLINGEN ET AL., "Use of Various Genetic Markers in Differentiation of <i>Mycobacterium bovis</i> Strains from Animals and Humans and for Studying Epidemiology of Bovine Tuberculosis", <u>Journal of Clinical Microbiology</u> , Vol. 32, No. 10, pp. 2425-2433, October 1994.	
	SAMPER ET AL., "Transmission between HIV-infected patients of multidrug-resistant tuberculosis caused by <i>Mycobacterium bovis</i> ", <u>Aids</u> , Vol. 11, No. 10, pp. 1237-1242, 1997, Rapid Science Publishers.	
	GORDON, S.V. ET AL., "Genomics of <i>Mycobacterium bovis</i> ", <u>Tuberculosis</u> (2001), Vol. 81(1/2), pp. 157-163, Harcourt Publishers Ltd.	
	BROSCH ET AL., "Genomics, Biology, and Evolution of the <i>Mycobacterium tuberculosis</i> Complex", <u>Molecular Genetics of Mycobacteria</u> , pp. 19-36, ASM Press, 2000, Washington DC.	
	FLETCHER ET AL., "Widespread Occurrence of <i>Mycobacterium tuberculosis</i> DNA from 18 <sup>th</sup> -19 <sup>th</sup> Century Hungarians", <u>American Journal of Physical Anthropology</u> , Vol. 120, pp. 144-152 (2003), Wiley Liss, Inc. 2003.	
	MAYS ET AL., "Paleopathological and Biomolecular Study of Tuberculosis in a Medieval Skeletal Collection from England", <u>American Journal of Physical Anthropology</u> , Vol. 114, pp. 298-311 (2001), Wiley-Liss, Inc.	
	SALO ET AL., "Identification of <i>Mycobacterium tuberculosis</i> DNA in a pre-Columbian Peruvian mummy", <u>Microbiology, Proc. Natl. Acad. Sci. USA</u> , Vol. 91, pp. 2091-2094, March 1994.	
	ROTHSCHILD ET AL., " <i>Mycobacterium tuberculosis</i> Complex DNA from an Extinct Bison Dated 17,000 Years before the Present", <u>Clinical Infectious Diseases</u> 2001, Vol. 33, pp. 305-311, Origins of Tuberculosis in North America, 1 August.	
	PARSONS ET AL., "Rapid and Simple Approach for Identification of <i>Mycobacterium tuberculosis</i> Complex Isolates by PCR-Based Genomic Deletion Analysis", <u>Journal of Clinical Microbiology</u> , Vol. 40, No. 7, pp. 2339-2345, July 2002, American Society for Microbiology.	
	EISENACH ET AL., "Polymerase Chain Reaction Amplification of a Repetitive DNA Sequence Specific for <i>Mycobacterium tuberculosis</i> ", <u>The Journal of Infectious Diseases</u> , 1990, Vol. 161, pp. 977-981, The University of Chicago, 1990.	
	THIERRY ET AL., "Characterization of a <i>Mycobacterium tuberculosis</i> Insertion Sequence, IS6110, and Its Application in Diagnosis", <u>Journal of Clinical Microbiology</u> , Vol. 28, No. 12, December 1990, pp. 2668-2673, American Society for Microbiology.	

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Sheet	3	of	4	Application Number	10/505,405
				Filing Date	August 24, 2004
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				Art Unit	Not assigned
				Examiner Name	Not assigned
				Attorney Docket Number	05394.0020-00000

	BRISSON-NOEL ET AL., "Diagnosis of tuberculosis by DNA amplification in clinical practice evaluation", <u>The Lancet</u> , Vol. 338, pp. 364-366, August 10, 1991.	
	CLARRIDGE III ET AL., "Large-Scale Use of Polymerase Chain Reaction for Detection of <i>Mycobacterium tuberculosis</i> in a Routine Mycobacteriology Laboratory", <u>Journal of Clinical Microbiology</u> , Vol. 31, No. 8, pp. 2049-2056.	
	GORMICAN ET AL., "Use of polymerase chain reaction for early identification of <i>Mycobacterium tuberculosis</i> in positive cultures", <u>J. Clin Pathol</u> 1992, Vol. 45, pp. 601-604, Department of Medical Microbiology, University College Hospital, Galway, Ireland, November 20, 1991.	
	COUSINS ET AL., "Use of Polymerase Chain Reaction for Rapid Diagnosis of Tuberculosis", <u>Journal of Clinical Microbiology</u> , Vol. 30, No. 1, January 1992, pp. 255-258, American Society for Microbiology.	
	DEL PORTILLO ET AL., "Amplification of a Species-Specific DNA Fragment of <i>Mycobacterium tuberculosis</i> and Its Possible Use in Diagnosis", <u>Journal of Clinical Microbiology</u> , Vol. 29, No. 10, pp. 2163-2168, October 1991, American Society for Microbiology.	
	FOLGUEIRA ET AL., "Polymerase chain reaction for rapid diagnosis of tuberculous meningitis in AIDS patients", <u>Neurology</u> 1994, Vol. 44, pp. 1336-1338.	
	FORBES ET AL., "Direct Detection of <i>Mycobacterium tuberculosis</i> in Respiratory Specimens in a Clinical Laboratory by Polymerase Chain Reaction", <u>Journal of Clinical Microbiology</u> , Vol. 31, No. 7, pp. 1688-1694, July 1993, American Society for Microbiology.	
	HERMANS ET AL., "Specific Detection of <i>Mycobacterium tuberculosis</i> Complex Strains by Polymerase Chain Reaction", <u>Journal of Clinical Microbiology</u> , Vol. 28, No. 6, June 1990, pp. 1204-1213, American Society for Microbiology.	
	KALTWASSER ET AL., "Enzymatic DNA amplification (PCR) in the diagnosis of extrapulmonary <i>Mycobacterium tuberculosis</i> infection", <u>Molecular and Cellular Probes</u> (1993) Vol. 7, pp. 465-470, Academic Press Limited.	
	KOCAGOZ ET AL., "Detection of <i>Mycobacterium tuberculosis</i> in Sputum Samples by Polymerase Chain Reaction Using a Simplified Procedure", <u>Journal of Clinical Microbiology</u> , Vol. 31, No. 6, pp. 1435-1438, June 1993, American Society for Microbiology.	
	KOLK ET AL., "Detection of <i>Mycobacterium tuberculosis</i> in Clinical Samples by Using Polymerase Chain Reaction and a Nonradioactive Detection System", <u>Journal of Clinical Microbiology</u> , Vol. 30, No. 10, pp. 2567-2575, October 1992, American Society for Microbiology.	
	KOX ET AL., "A More Reliable PCR for detection of <i>Mycobacterium tuberculosis</i> in Clinical Samples", <u>Journal of Clinical Microbiology</u> , Vol. 32, No. 3, pp. 672-678, March 1994, American Society for Microbiology.	
	LIU ET AL., "Rapid diagnosis of tuberculous meningitis by a simplified nested amplification protocol", <u>Neurology</u> , Vol. 44, pp. 1161-1164, 1994.	
	THIERRY ET AL., "Characterization of a <i>Mycobacterium tuberculosis</i> Insertion Sequence. IS6110, and Its Application in Diagnosis", <u>Journal of Clinical Microbiology</u> , Vol. 28, No. 12, pp. 2668-2673, American Society for Microbiology.	
	MILLER ET AL., "Evaluation of Gen-Probe Amplified Mycobacterium Tuberculosis Direct Test and PCR for Direct Detection of <i>Mycobacterium tuberculosis</i> in Clinical Specimens", <u>Journal of Clinical Microbiology</u> , Vol. 32, No. 2, pp. 393-397, February 1994, American Society for Microbiology.	
	REISCHL, ET AL., "PCR-Based Detection of Mycobacteria in Sputum Samples Using a Simple and Reliable DNA Extraction Protocol", <u>Benchmarks</u> , Vol. 17, No. 5 (1994), pp. 844-845.	
	SCHLUGER ET AL., "Clinical Utility of the Polymerase Chain Reaction in the Diagnosis of Infections due to <i>Mycobacterium tuberculosis</i> ", <u>Chest</u> 105/4/April 1994, pp. 1116-1121.	
	SHAWAR ET AL., "Detection of <i>Mycobacterium tuberculosis</i> in Clinical Samples by Two-Step Polymerase Chain Reaction and Nonisotopic Hybridization Methods", <u>Journal of Clinical Microbiology</u> , Vol. 31, No. 1, pp. 61-65, January 1993, American Society for Microbiology.	
	URDEA ET AL., "A Comparison of non-radioisotopic hybridization assay methods using fluorescent, chemiluminescent and enzyme labeled synthetic oligodeoxynucleotide probes", <u>Nucleic Acids Research</u> , Vol. 16, No. 11, pp. 4937-4956, 1988.	
	SANCHEZ-PESCADOR ET AL., "Rapid Chemiluminescent Nucleic Acid Assays for Detection of TEM-1 $\beta$ -Lactamase-Mediated Penicillin Resistance in <i>Neisseria gonorrhoeae</i> and Other Bacteria", <u>Journal of Clinical Microbiology</u> , Vol. 26, No. 10, pp. 1934-1938, October 1988, American Society for Microbiology.	
	MATTHEWS ET AL., "Analytical Strategies for the Use of DNA Probes", Review, <u>Analytical Biochemistry</u> , Vol. 169, pp. 1-25, 1988, Academic Press, Inc., 1988.	
	SCHMIDT, "Opening Remarks", <u>Reviews of Infectious Diseases</u> , Vol. 11, Supp. 2, March-April 1989, Fogarty International Center, National Institutes of Health, Bethesda, Maryland.	

Complete if Known

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet	4	of	4	Application Number	10/505,405
				Filing Date	August 24, 2004
				First Named Inventor	Stewart Cole
				Art Unit	Not assigned
				Examiner Name	Not assigned
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		MERLICH ET AL., Molecular evidence for tuberculosis in an ancient Egyptian mummy", <u>The Lancet</u> , Vol. 350, p. 1404, November 8, 1997, Departments of Pathology, Anthropology, and Radiology, Ludwig-Maximilians-Universitat München, 80337 Germany.	
		RADHAKRISHNAN ET AL, "Implications of Low Frequency of IS6110 in Fingerprinting Field Isolates of <i>Mycobacterium tuberculosis</i> from Kerala, India", <u>Journal of Clinical Microbiology</u> , Vol. 39, No. 4, p. 1683, April 2001, American Society for Microbiology, 2001.	

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.